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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,559	08/16/2006	Klaus Abraham-Fuchs	32860-001071/US	8517

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EXAMINER	
PAULS, JOHN A	

ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
08/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,559	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	JOHN A. PAULS	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 16 August, 2006.

2. Claims 1 - 20 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statement filed on 16 August, 2006 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

Amendment

4. The preliminary amendment filed on 16 August, 2006 has been entered.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1 - 20 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. The claim does not require that the steps of the method be performed by a particular machine; therefore the method is not eligible as a statutory process.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1 – 6 and 9 - 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Marks et al. (US PGPUB 2005/0010451 A1). Examiner notes that Marks et al. has a priority date of 7 May, 2003 based on the disclosure in provisional application 60/468,912.

CLAIM 1

Marks as shown discloses a clinical trial management system with the following limitations:

- *determining a quality control parameter assigned to each medical data record in a similar manner;* (see at least Marks paragraph 0041, 0042 and 0043);
- *evaluating the quality control parameters on a basis of comparison criteria;* (see at least Marks paragraph 0019, 0043 and 0056).

Examiner notes that Marks discloses that the system monitors clinical research data and compares it to criteria. Some examples of criteria, which may be individualized for each site, include: reaching a target number of study subject registered by a particular deadline; number of adverse events and concerns for subject safety.

CLAIM 2

Marks as shown discloses the limitations shown above relative to Claim 1. Additionally, Marks discloses the following limitations:

- *determining, from the quality control parameter assigned to a medical data record, a quality level for every medical data record on a basis of quality criteria;* (see at least Marks paragraph 0011, 0012, 0043, 0056, 0057 and 0059).

Examiner notes that Marks discloses that the system monitors clinical research data and compares it to criteria. Sites are statistically analyzed for screening and failure rates, enrollment rates and follow-up rates as examples. Sites showing poor performance can be removed or disqualified from future studies.

CLAIMS 3, 4 and 12

Marks as shown discloses the limitations shown above relative to Claim 2. Additionally, Marks discloses the following limitations:

- *specifying boundary values, assigned to the medical project for the quality control parameters, wherein the quality level of the medical data records is determined on the basis of the boundary values;* (see at least Marks paragraph 0068 and 0069);
- *the medical data records are collected by project managers and wherein the quality levels assigned to the medical data records are assigned to the project managers;* (see at least Marks paragraph 0006, 0018, 0098 and 0100).

Examiner notes that Marks discloses that study domains may include participating sites or a single physician investigator. It is inherent that a participating site would have a responsible party or project manager who would be assigned responsibility for the site's performance. It is further noted that a "project manager" need not be a person, but could be construed to be an entity (i.e. a management organization).

CLAIMS 5, 6, 13 and 14

Marks as shown discloses the limitations shown above relative to Claim 4 and 12 respectively. Additionally, Marks discloses the following limitations:

- *the project managers are remunerated for running the project in accordance with the quality levels assigned to them;* (see at least Marks paragraph 0012, 0016 and 0018);
- *the project managers are entered in a ranking database in accordance with the quality levels assigned to them;* (see at least Marks paragraph 0056 and 0057).

Examiner notes that Marks discloses that participating sites may be included or excluded from future studies as a result of their quality rating (i.e. an in/out ranking)

CLAIMS 9 and 10

Marks as shown discloses the limitations shown above relative to Claim 2. Additionally, Marks discloses the following limitations:

- *the medical data records are determined in the course of a clinical workflow, and wherein an electronic workflow management system controls the clinical workflow depending on the quality control parameters determined;* (see at least Marks paragraph 0011 and 0012);
- *the procedural rules for at least one of a current and a future medical project is specified depending on the quality control parameters determined;* (see at least Marks paragraph 0056 - 0058).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

    1. Determining the scope and contents of the prior art.
    2. Ascertaining the differences between the prior art and the claims at issue.
    3. Resolving the level of ordinary skill in the pertinent art.
    4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 7, 8 and 15 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marks et al. (US PGPUB 2005/0010451 A1).

CLAIMS 7 and 15 - 17

Marks as shown discloses the limitations shown above relative to Claims 2, 4, 6 and 12 respectively. Additionally, Marks discloses the following limitations:

- *the quality levels assigned to the medical data records are stored in a database;* (see at least Marks paragraph 0057 and 0063).

Marks may or may not specifically disclose the following limitation:

- *with each quality level a description associated with it is stored in the database.*

However, Marks does disclose that various descriptions are stored in the database, for example, descriptions of the fields in an adverse event report. Therefore, it would be obvious to one of ordinary skill in the art to have modified Marks so that descriptions of the quality levels were stored in the database, in order to provide a reference of the quality level definitions, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIM 8

Marks as shown discloses the limitations shown above relative to Claim 7. Marks may or may not specifically disclose the following limitations:

- *data characterizing the patient collective assigned to the quality level are stored as a description in the database.*

However, Marks does disclose that various descriptions are stored in the database, for example, descriptions of the fields in an adverse event report. Therefore, it would be obvious to one of ordinary skill in the art to have modified Marks so that descriptions of the patient collectives were stored in the database, in order to provide a reference of the patient collective definitions, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIMS 18 and 19

Marks as shown discloses the limitations shown above relative to Claim 1. Additionally, Marks discloses the following limitations:

- *the medical data records are determined in the course of a clinical workflow, and wherein an electronic workflow management system controls the clinical workflow depending on the quality control parameters determined;* (see at least Marks paragraph 0011 and 0012);

- *the procedural rules for at least one of a current and a future medical project is specified depending on the quality control parameters determined;* (see at least Marks paragraph 0056 - 0058).

CLAIMS 11 and 20

Marks as shown discloses the limitations shown above relative to Claims 1 and 2 respectively. Additionally, Marks discloses the following limitations:

- *quality control parameters comparison criteria and evaluation methods assigned thereto for different medical projects are stored as objects in a toolset, and wherein for quality control of a particular medical project suitable objects are selected from the toolset and used;* (see at least Marks paragraph 0043 and 0056 - 0058).

Conclusion

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **571-270-5557.** The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

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Washington, D.C. 20231

or faxed to 571-**273-8300**.

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/J. A. P./
Examiner, Art Unit 3686
Date: 27 July, 2010

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686